

### **REMARKS**

Claims 1 and 3-71 are pending in the application with claims 1 and 3-34 under active consideration, claims 35-71 having been withdrawn as drawn to non-elected subject matter. By the present communication, claims 1, 3-7, 10-13, 15-17, 20, 21, and 24-30 have been amended. Claims 1, 5, 10, 13, 16, 17, 20, 21, 24-26, 28, and 30 are amended to correct typographical errors, to update claim dependency, or include sequence identifiers and are consistent with the suggestions of the Examiner. Claim 6 is amended to reflect that one concentration of inhibitor does not inhibit Homer binding whereas another concentration does inhibit binding. This amendment is supported by, for example, paragraph [0035] of the specification. The amendments to claims 11 and 29 are supported by, for example, paragraphs [0033] and [000100]. These amendments add no new matter as the claim language is fully supported by the specification and original claims. In view of these amendments, claim 23 and previously withdrawn claims 35-71 have been canceled without prejudice or disclaimer. Subsequent to the entry of the present amendment, claims 1, 3-22, and 24-30 will be under consideration.

#### **I. Objections to the Specification**

The Examiner's objection to the specification as allegedly containing various informalities is noted. Specifically, the Examiner asserts that paragraphs [0099] and [0103] cite to figures but the figure number is missing. These informalities have been corrected by the present amendments to specification. Accordingly, reconsideration and withdrawal of this objection are respectfully requested.

#### **II. Claim Objections**

Claims 25 and 26 are each objected to on the basis of each depending from itself. This apparent typographical error has been corrected by the present amendments to the claims.

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Specifically, as amended herein, claims 25 and 26 depend from claims 1 and 25, respectively. Accordingly, reconsideration and withdrawal of this objection are respectfully requested.

Claim 5 is objected to because the word “effect” is misspelled. This apparent typographical error has been corrected by the present amendments to the claims. Accordingly, reconsideration and withdrawal of this objection are respectfully requested.

Claim 20 is objected to on the basis that the word “a” on line 3 of the claim should be “the.” In order to reduce the issues and expedite prosecution, claim 20 has been amended consistent with the Examiner’s suggestion. Accordingly, reconsideration and withdrawal of this objection are respectfully requested.

Claim 21 is objected to on the basis that the word “die” on line 2 of the claim should be “the.” This apparent clerical error has been corrected by the present amendments to the claims. Accordingly, reconsideration and withdrawal of this objection are respectfully requested.

Claim 28 is objected to on the basis that the phrase “as set from” on line 1 of the claim should be “is set forth.” This apparent clerical error has been corrected by the present amendments to the claims. Accordingly, reconsideration and withdrawal of this objection are respectfully requested.

The Examiner has objected to claims 16, 17, and 28 based on the reference to accession numbers of public sequence databases, and has required that the accession numbers be replaced with sequence identifiers. The Examiner has further required that the Sequence Listing be updated to include the sequences corresponding to these accession numbers. In order to reduce the issues and expedite prosecution, claims 16, 17, and 28, therefore, have been amended to replace the accession numbers with sequence identifiers. Moreover, a replacement Sequence Listing is submitted herewith, which includes the sequences corresponding to the subject accession number. No new matter is introduced by the subject amendments as the sequences are publicly known and are supported by reference to accession numbers. Accordingly, reconsideration and withdrawal of this objection are respectfully requested.

Claim 11 is objected to as allegedly being in improper dependent form for failing to further limit the subject matter of the claim from which it depends. Contrary to the allegation as set forth in the Action, this claim further defines the manner by which binding may be determined (i.e., step iii) of claim 1) and thus is properly dependent. As would be readily recognized by the skilled artisan, binding between Homer and the “at least one protein or peptide” (as in claim 1, step iii)) may be determined by any number of methods known to the skilled artisan. For example, binding may be determined by a standard binding assay, immunoprecipitation of the complex formed by Homer and the bound protein or peptide (e.g., claim 4), or by using any of the “endpoint assays” recited in the claim 11. Moreover, claim 11 has been amended herein to emphasize that binding is determined by the endpoint assays recited therein. Thus, it is respectfully submitted that claim 11 is further limiting of claim 1 and is therefore, properly dependent. Accordingly, reconsideration and withdrawal of this objection are respectfully requested.

### **III. Rejections under 35 U.S.C. §112, First Paragraph (Written Description)**

The rejection of claims 31-34 under 35 U.S.C. §112, first paragraph for allegedly failing to satisfy the written description requirement is respectfully traversed.

The Examiner asserts that claims 31-34 refer to a modulating agent and its use without providing a “true technical characterization” and further asserts that “no such specific agent is defined in the specification” (Office Action at page 4). To the contrary, it is respectfully submitted that the modulating agents of claims 31-34 are fully supported by the present specification.

Specifically, the specification provides, at paragraph [00079], that the phrase “modulating agents” refers to “a chemical composition which varies the binding, activity or

function of a Homer protein.” The specification further provides that such modulating agents may function as neuroprotective agents (e.g., paragraph [0023]) or immunosuppressive agents (e.g., paragraph [00025]). The specification also provides that the agents or compounds which may be screened by the invention methods include “peptides, antibodies and fragments thereof, and other organic compounds (e.g., peptidomimetics)” (paragraph [000135]), soluble peptides such as members of random peptide libraries, combinatorial chemistry-derived libraries of amino acids, phosphopeptides, antibodies (paragraph [000136]), or small organic molecules able to cross the blood-brain barrier (paragraph [000137]). Moreover, computer models may be employed in a rational drug design approach to identify candidate compounds for screening or to modify those compounds identified as modulating agents to improve efficacy (paragraphs [000138] – [000143]). Further, the specification provides, assays by which candidate compounds may be screened for activity in modulating Homer signaling (e.g., paragraphs [000117]-[000120]). Thus, it is respectfully submitted that the skilled artisan could readily identify the agents of claims 31-34.

Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

### **III. Rejections under 35 U.S.C. §112, First Paragraph (Enablement)**

The rejection of claims 31-34 under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the enablement requirement is respectfully traversed.

The Examiner asserts that the specification allegedly fails to disclose any particular structure for the claimed agent, nor does the specification provide any guidance or working examples. Contrary to the Examiner’s assertion, it is respectfully submitted that based on the teachings of the specification and that which was known in the art at the time of filing of the

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application, the skilled artisan could readily use the invention methods to identify the agents of claims 31-34.

As discussed above, the specification provides a description of compounds which may be screened by the invention methods for identifying agents that modulate Homer signaling (see e.g., paragraphs [000135] – [000137]) as well as computer models for identifying candidate compounds or improving those already confirmed to be Homer modulating agents (see e.g., paragraphs [000138] – [000143]). The specification further provides assays by which candidate compounds may be screened for activity in modulating Homer signaling (e.g., paragraphs [000117] - [000120]). Finally, activity of identified modulating agents as neuroprotective or immunosuppressive agents can be confirmed using assays well-known to the skilled artisan. Thus, it is respectfully submitted that the skilled artisan could readily use the invention methods and those methods known in the art to identify the agents of claims 31-34.

Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

#### **IV. Rejections under 35 U.S.C. §112, Second Paragraph**

Claims 1, 11, and 29 stand rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for various reasons. Applicants respectfully traverse the rejection as applied to the pending claims.

Specifically, the Examiner asserts that the “protein or peptide” recited in claim 1, line 8 (i.e., step ii) forms a mixture with the reagents of step (i) and thus, this phrase should be replaced with the phrase “mixture formed in.” Without acquiescing to the reasoning offered in the Action and in order to reduce the issues and expedite prosecution, claim 1 has been amended consistent with the Examiner’s suggestion. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner further asserts that the determining step of claim 1 (i.e., step iii) should include a comparison to a control, in order to determine an increase or decrease in binding. Without acquiescing to the reasoning offered in the Action and in order to reduce the issues and expedite prosecution, claim 1 has been amended consistent with the Examiner's suggestion. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Claim 11 is rejected as indefinite for the recitation of a series of endpoint assays, allegedly having no antecedent basis. It is respectfully submitted that the endpoint assays further define the methods by which binding of Homer can be determined. Indeed, claim 11 has been amended herein to emphasize that binding is determined by the endpoint assays recited therein. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Claim 29 is rejected as indefinite for the recitation of a Homer protein with point mutations. Without acquiescing to the reasoning offered by in the Action, this rejection has been rendered moot by the amendments to claim 29, in which the language at issue has been replaced. This amendment is supported by the specification at, for example, paragraph [00100]. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

#### **V. Rejections under 35 U.S.C. §102(b)**

The rejection of claims 6, 7, and 10 under 35 U.S.C. §103 as allegedly anticipated by Xiao *et al.* (*Current Opinion in Neurobiology* 10:370-4, 2000) is respectfully traversed. As a preliminary matter, claim 10 as amended herein no longer depends from claim 7 and instead, depends from claim 9. Accordingly, the rejection as applied to claim 10 has been rendered moot.

The Examiner asserts that Xiao teaches "a role for Homer complexes in signal transduction, synaptogenesis and receptor trafficking" and "a method to study Homer complexes by immunoprecipitation in the absence of a peptidylproline cis-trans isomerase

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(PPIase) (read as wherein the PPIase inhibitor is present in at least two concentration[s], wherein at least one concentration of the inhibitor does not inhibit Homer binding to the at least one protein or peptide)” (Office Action at pp 6-7, bridging paragraph).

The Examiner previously acknowledged that Xiao does not teach a role of PPIases in Homer complexes. Indeed, prior to the work of the present Applicants, the involvement of PPIases in Homer signaling was not known. Therefore the inclusion of a PPIase inhibitor in an assay to identify agents that modulate a Homer signaling pathway would not have been appreciated by the skilled artisan. Accordingly, claim 6, as presently amended, reflects that one concentration of the inhibitor does not inhibit Homer binding, while another concentration of inhibitor does inhibit binding. Support for this amendment may be found at for example, paragraph [0035]. Therefore, claim 6 and dependent claim 7 are not anticipated by Xiao because a PPIase inhibitor is present at a concentration wherein Homer binding is inhibited. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

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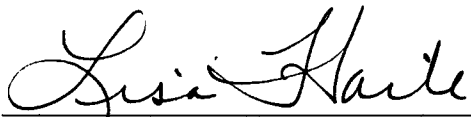
### Conclusion

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

The Commissioner is hereby authorized to charge the amount of \$180.00 for the Information Disclosure Statement fee to Deposit Account No. 07-1896. No other fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee, or credit any overpayment, to Deposit Account No. 07-1896.

Respectfully submitted,

Date: February 5, 2008



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